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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/519,376      | 12/20/2004  | Lanna Li             | 100681-1P US        | 4784             |

52286 7590 05/03/2007  
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Pittsburgh, PA 15219-2502

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| EXAMINER |
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OH, TAYLOR V

|          |              |
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| ART UNIT | PAPER NUMBER |
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1625

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| MAIL DATE | DELIVERY MODE |
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05/03/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/519,376

Applicant(s)

LI, LANNA

Examiner

Taylor Victor Oh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4 is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 2/10/05.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

The Status of Claims:

Claims 1-10 are pending.

Claims 1-3 and 5-10 have been rejected.

Claim 4 is allowable.

DETAILED ACTION

1. Claims 1-10 are under consideration in this Office Action.

Priority

2. It is noted that this application is a 371 of PCT/GB03/02591 (06/17/2003), which has foreign priority documents, Sweden 0201935-2 filed on 06/20/2002 .

Drawings

3. None.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 5-7, and 10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter

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which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In the claim 1, the term " prodrug" is recited. However, the specification has not described how any prodrug is converted into its active form in the body under any circumstances. This description is essential to the claimed invention because it allows to distinguish identifying characteristics sufficient show that the applicant was in possession of the claimed invention, and the claim ,as a whole, may not be adequately described where the invention is described solely in terms of a process of its conversion coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its functional language. For example, the specification merely mentions that the term "prodrug" refers to any compound which , upon administration to a host, is converted or metabolized to an active compound. Furthermore, Medical dictionary defines the term as a class of drugs, initially in active form, that are converted into active form in the body by normal metabolic processes. There are no examples for the class of prodrugs applicable to the claimed invention; not to mention, how the prodrugs are converted or metabolized to the active compound of the present invention.

Therefore, the specification has failed to describe the subject matter in the claims as to the relationship between the prodrugs and their final active claimed compounds during the preparation process. Therefore, an appropriate correction is required.

In claim 6, the phrase " a method of treating and preventing insulin resistance " is recited. However, the specification does not describe how to prevent diabetes in general and furthermore, there are two different kinds diabetes: type 1 and type 2. Diabetes mellitus type 1 is related to a generic defect (an autoimmune disease) ,whereas Diabetes mellitus type 2 is linked to a life style (obesity) led to insulin resistance. Diabetes mellitus type 1 needs on-going insulin injections; therefore, the only solution so far is the transplant of the pancreas. From this information, there are no showings of any evidence for "preventing diabetes type 1 and type 2 " at the same time. Furthermore, the contemporary knowledge of the art does not teach " how to prevent " for alleged Diabetes. If we could prevent all the possible permutations and combinations of the above, nobody would be sick. In addition, more than routine experimentation is involved. See In re Armbruster 185 USPQ 204 (CCPA 1985) and Angstadt et al. , 190 USPQ 152 (CCPA 1990). Therefore, the specification has failed to support enablement for the method for treating and/or preventing insulin resistance. Therefore, an appropriate correction is required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7–8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 provides for the use of a compound, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process

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applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 7 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim 8 recites the limitation "  $R^1$ ,  $R^2$ ,  $R^3$ , W and n are as previously defined" in line 4. There is insufficient antecedent basis for this limitation in the claim.

In claim 8 , the phrase"  $R^1$ ,  $R^2$ ,  $R^3$ , W and n are as previously defined" is recited. This is vague and indefinite because those variables are undefined.


Regarding claim 10, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Taylor Victor Oh, MSD, LAC  
Primary Examiner  
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4/30/07